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10/520,698	08/02/2005	Andre Francois Gorenflot	I-2002.010 US	2601

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PATENT DEPARTMENT
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EXAMINER	
GANGLE, BRIAN J	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,698	GORENFLOT ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,23-26 and 29-39* is/are pending in the application.

4a) Of the above claim(s) *32-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15, 23-26, and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's remarks and amendment, filed 8/8/2007, are acknowledged. Claim 15 has been amended. Claims 16-22 and 27-28 have been cancelled. Claims 29-39 have been added.

Election/Restrictions

Newly submitted claims 32-39 are directed to an invention that lacks unity with the invention originally claimed for the following reasons: Claims 32-39 belong to non-elected Group I, as set forth in the previous office action. As set forth previously, the technical feature linking the inventions does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art. Applicant asserts that the search for the elected invention would encompass the search for claims 32-39; however, search burden is not a consideration when determining whether restriction is proper under he PCT rules for lack of unity.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-39 are withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 15, 23-26, and 29-39 are pending. Claims 15, 23-26, and 29-31 are currently under examination.

Objections Withdrawn

The objection to the specification for non-compliance with the sequence requirements is withdrawn in light of applicant's amendment.

The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code on page 8, is withdrawn in light of applicant's amendment thereto.

The objection to the specification for the use of trademarks is withdrawn in light of applicant's amendment thereto.

The objection to claims 15-26 because the claims are drawn, in part, to nonelected subject matter is withdrawn in light of applicant's amendment thereto.

The objection to claim 18 because the claim contains genus names, which should be italicized is withdrawn in light of applicant's amendment thereto.

Objections Maintained

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections Withdrawn

The rejection of claims 15-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of applicant's amendment thereto.

The rejection of claims 15-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in light of applicant's amendment thereto.

Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 15 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "combining a heterologous hydrophobic polypeptide to the N-terminus and/or the C-terminus of a core polypeptide," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 15 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "hydrophobic polypeptide," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein the heterologous hydrophobic peptide is from an N-terminal hydrophobic sequence," is withdrawn. The cancellation of the claim renders this rejection moot.

The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein the heterologous hydrophobic peptide is from an internal hydrophobic sequence," is withdrawn. The cancellation of the claim renders this rejection moot.

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein the heterologous hydrophobic peptide is from an C-terminal hydrophobic sequence," is withdrawn. The cancellation of the claim renders this rejection moot.

The rejection of claims 19-21 under 35 U.S.C. 112, second paragraph, because they recite the limitation "hydrophobic peptide," is withdrawn. The cancellation of the claim renders this rejection moot.

The rejection of claims 15-19, 23-25 under 35 U.S.C. 102(b) as being anticipated by Chandrashekar *et al.* (US Patent 5,854,051, 1998), is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 24-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained for the reasons set forth in the previous office action.

Applicant argues: that the claims have been amended and the rejections are believed to be moot.

Applicant's arguments have been fully considered and deemed non-persuasive.

The amendments have not addressed the issues presented in the rejection.

As outlined previously, the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are drawn to methods of preparing vaccines by mixing a fusion protein comprising a *Babesia* Bd37 polypeptide and a decay accelerating factor peptide with a saponin adjuvant and a pharmaceutically acceptable carrier.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that applicant has possession the claimed invention. To adequately describe the genus of vaccines comprising a *Babesia* Bd37 polypeptide and a decay accelerating factor peptide with a saponin adjuvant, applicant must adequately describe the antigenic determinants (immunoepitopes) that elicit a protective immune response against a given pathogen. The specification discloses Bd37 as an antigen of *Babesia divergens*, but does not disclose any other fusion proteins containing protective epitopes that are capable of eliciting a protective immune response against any other pathogen. Applicant appears to be relying on a non-patent literature journal article to provide support for the sequence of Bd37. This sequence is deemed to be essential material and according to 37 CFR 1.57, "essential material " may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material

by reference. The specification further does not disclose distinguishing and identifying features of a representative number of members of the genus of fusion proteins to which the claims are drawn, such as a correlation between the structure of the immunoepitope and its recited function (i.e. eliciting protective immunity against a given pathogen), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of fusion proteins. Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of immunoepitopes to which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of fusion proteins containing protective epitopes.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to

practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan *et al.* (Nature Biotechnology 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan *et al.* recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan *et al.*, an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of immunoepitopes, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of fusion proteins containing protective epitopes. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of vaccines comprising fusion proteins

to which the claim refers.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 24-26 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "preparing a vaccine," is maintained for the reasons set forth in the previous office action. What is the vaccine intended to protect against?

The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein at least one additional immunoactive component is combined with said vaccine," is maintained for the reasons set forth in the previous office action. It is not clear whether this is an active method step and when this step should occur.

The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein said vaccine is freeze-dried," is maintained for the reasons set forth in the previous office action. It is not clear whether this is an active method step and when this step should occur.

New Claim Rejections

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of preparing a vaccine against *Babesia divergens*, comprising mixing a immunogenic composition comprising a saponin adjuvant and a fusion protein comprising a *Babesia* Bd37 polypeptide and a decay accelerating factor peptide with a saponin and a pharmaceutically acceptable carrier, does not reasonably provide enablement for the claims as drawn. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn to methods of preparing a vaccine comprising admixing an immunogenic composition with a pharmaceutically acceptable carrier. Said immunogenic composition must comprise a saponin adjuvant and a fusion protein comprising a *Babesia* Bd37 polypeptide and a decay accelerating factor peptide.

Breadth of the claims: The claims encompass any *Babesia* Bd37 polypeptide and any decay accelerating factor peptide, as well as encompassing protective immunity against any pathogen or disease in any animal.

Guidance of the specification/The existence of working examples: The fusion protein Bd37-DAF is shown to have protective efficacy against *Babesia divergens* Munich in a challenge experiment in gerbils. However, the specification does not provide any indication that said fusion protein would be effective as a vaccine against any other pathogen.

State of the art: While the skill in the art of immunology is high, to date, prediction of a specific immune response for any given composition in any given animal is quite unpredictable. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie *et al.* (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome **and form immunoepitopes**. Bowie *et al.* further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie *et al.* further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Additionally, as evidenced by Greenspan *et al.* (Nature Biotechnology 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan *et al.* recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan *et al.*, an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a particular immune response to a given pathogen can only be identified empirically. This constitutes undue experimentation. Clearly, those of skill in the art would have no expectation that an antigen from *Babesia* would provide any protective effect against any other pathogen. Therefore, given the lack of success in the art, the lack of working examples commensurate in scope to the claimed invention and the unpredictability of the generation of antibodies to a particular epitope, the specification, as filed, does not provide enablement for the full scope of the claims.

Claims 29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The amino acid sequence of the *Babesia* BD37 polypeptide which is associated with NCBI accession number CAD19563 is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The sequence associated with accession numbers such as NCBI CAD19563 is fluid and can be changed after submission. Therefore, without knowing the sequence at the time of invention, one of skill in the art would not be able to identify the amino acid sequence required in the claimed fusion protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 31 are rendered vague and indefinite by the use of the terms "NCBI accession no. CAD19563." This term refers to an accession number for an amino acid sequence. However, the sequences associated with a given accession number can be modified, thereby rendering the scope and limitations of the claims uncertain.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15, 23-26, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caras (WO 89/01041, 1989, IDS filed 1/7/2005) in view of Carcy *et al.* (Infect. Immun., 63:811-817, 1995, IDS filed 1/7/2005) and Gupta *et al.* (Vaccine, 13:1263-1276, 1995).

The instant claims are drawn to methods of preparing an immunogenic composition comprising combining a saponin adjuvant in a free form with a fusion protein comprising a *Babesia* Bd37 polypeptide and a decay accelerating factor peptide (claim 15); wherein the saponin is Quillaja (claim 23); wherein a vaccine is made by combining said composition with a pharmaceutically acceptable carrier (claim 24); wherein said vaccine comprises at least one additional immunoactive component (claim 25); wherein said vaccine is freeze-dried (claim 26); wherein the *Babesia* Bd37 polypeptide comprises amino acids 25-316 of NCBI accession number CAD19563 (claims 29 and 31); and wherein the decay accelerating factor peptide comprises SEQ DI NO:14 (claims 30 and 31).

Caras discloses a fusion protein comprising decay accelerating factor and any chosen antigen (see page 15, lines 20-30). Said fusion protein contains SEQ ID NO:14 (see Figure 3) Caras also teaches that DAF proteins are generally stored after lyophilization (page 26, lines 30-35).

Caras differs from the instant claims in that the antigen in the fusion protein is not disclosed as Bd37 and no saponin adjuvant is included in the composition.

Carcy *et al.* disclose a polypeptide from *Babesia divergens* known as Bd37. Carcy *et al.* state that Bd37 appears to be a potential immunogen in a vaccine against babesiosis (see page 811, column 2, paragraph 1). According to the instant specification, the Bd37 polypeptide disclosed by Carcy *et al.* has the sequence of NCBI accession number CAD19563 (page 14, lines 25-35).

Gupta *et al.* disclose adjuvants including Quil A, which is widely used in veterinary vaccines (page 1271, column 1, paragraph 4). Quil A is a heterogeneous mixture of saponins (page 1271, column 1, paragraph 4). Gupta *et al.* also state that adjuvants help antigens to elicit an early, high, and long-lasting immune response with less antigen, thus saving on vaccine production costs (see abstract).

Therefore, it would have been obvious to the person of ordinary skill in the art, at the time of invention, to use Bd37 as the antigen in the fusion protein of Caras because Bd37 is a vaccine candidate antigen. One would also have been motivated to include a saponin adjuvant because adjuvants antigens to elicit an early, high, and long-lasting immune response with less antigen, thus saving on vaccine production costs. With regard to claim 25, Quil A contains

multiple saponins; therefore, a composition with Quil A would include a saponin and an additional immunoactive component (another saponin).

One would have had a reasonable expectation for success because Caras states that any antigen can be used in their fusion protein. In addition, Gupta *et al.* disclosed that Quil A has been widely used in veterinary vaccines.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle
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ROBERT A. ZEMAN
PRIMARY EXAMINER